



JUL 24 2000

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Re: Patent Term Extension  
Application for  
U.S. Patent No. 5,196,444

# 24

## NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,196,444, which claims the human drug product ATACAND® (candesartan cilexetil) and a method of use of ATACAND®, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 413 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of 413 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of March 2, 1999 (64 Fed. Reg. 10156). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (686) + 401 \\ &= 744 \text{ days}\end{aligned}$$

Since the regulatory review period began June 15, 1995, after the patent issue date (March 23, 1993), the entire period has been considered in the above determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 744 days, would extend the patent from April 18, 2011 (35 U.S.C. § 154) to May 1, 2013, which is beyond the 14-year limit (the approval date is June 4, 1998, thus the 14 year limit is June 4, 2012). The period of extension is thus limited to June 4, 2012, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, April 18, 2011, to and including June 4, 2012, or 413 days.

The limitations of 35 U.S.C. § 156(g)(6) do not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.: 5,196,444  
Granted: March 23, 1993

Original Expiration Date<sup>1</sup>: April 18, 2011

Applicant: Takehiko Naka, et al.

Owner of Record: Takeda Chemical Industries Ltd.

Title: 1-(Cyclohexyloxycarbonyloxy) Ethyl 2-Ethoxy-1-[[2'-(1H-Tetrazol-5-yl) Biphenyl-4-yl] Methyl]Benzimidazole-7-Caroxylate and Compositions and Method of Pharmaceutical Use Thereof

Classification: 514/167

Product Trade Name: ATACAND® (candesartan cilexetil)

Term Extended: 413 days

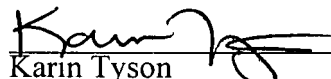
Expiration Date of Extension: June 4, 2012

Any correspondence with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents  
Box Patent Ext.  
Washington, D.C. 20231

By FAX: (703) 308-6916  
Attn: Special Program Law Office

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.

  
Karin Tyson  
Senior Legal Advisor  
Special Program Law Office  
Office of the Deputy Assistant Commissioner  
for Patent Policy and Projects

cc: David T. Read RE: ATACAND® (candesartan cilexetil)  
Acting Director Regulatory Policy Staff, CDER FDA Docket No.: 98E-0839  
Food and Drug Administration  
1451 Rockville Pike, HFD-7  
Rockville, MD 20852

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<sup>1</sup>Subject to the provisions of 35 U.S.C. § 41(b).